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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,046	02/03/2004	Brian Hague	CP246	2324
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CEPHALON, INC. 41 MOORES ROAD PO BOX 4011 FRAZER, PA 19355			EXAMINER BARHAM, BETHANY P	
			ART UNIT	PAPER NUMBER
			1615	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/771,046	HAGUE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bethany P. Barham	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 11, 15-20, 22-25 and 27-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11, 15-20, 22-25 and 27-43 is/are rejected.
- 7) ☒ Claim(s) 20, 22-25, 27-29, and 42 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Summary*

Receipt of Applicant's Response and Amended Claims filed on 10/16/2006 is acknowledged. Claims 1-5, 11, 15-20, 22-25, and 27-43 are pending. Claims 1-5, 11, 15-20, 22-25, and 27-43 are rejected.

Due to applicants claim amendments, the 102/103 rejections of record (06/22/2006) are hereby **withdrawn**. However, the 35 USC 112 rejections of record (06/22/2006) are hereby **maintained**.

### **Objections**

Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The essential elements of the instant independent claim 1 are: (1) fentanyl or its pharmaceutically acceptable salts, (2) a buffer, (3) an excipient, (4) wherein the composition essentially sugar-free. Since claim 20 is dependent any one of claims 3-19, which depend from claim 1 and is directed to a composition that "fentanyl or its pharmaceutically acceptable salts" this is not further limiting.

Art Unit: 1615

Claims 22-25 and 27-29 are objected to under 37 CFR 1.75(c), as being of improper dependent form for being dependent or multiple dependent on cancelled claims 21 and 26. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 42 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The essential elements of the instant independent claim 1 are: (1) fentanyl or its pharmaceutically acceptable salts, (2) a buffer, (3) an excipient, (4) wherein the composition essentially sugar-free. Since claim 42 is dependent from claim 1 and is directed to a composition that "contains a buffer" this is not further limiting.

### ***MAINTAINED REJECTIONS***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claim 43 omits an essential element of

independent claim 1, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is a "buffer" as set forth in the instant claim 1. The essential elements of the instant claim 1 are: (1) fentanyl or its pharmaceutically acceptable salts, (2) a buffer, (3) an excipient, (4) wherein the composition essentially sugar-free. Since the instant claim 43 is dependent on claim 1 (buffer required), the examiner respectfully submits that it omits an essential element.

### **Response to Arguments**

Applicant traverses the rejection and argues that the buffer of claim 1 is important to the invention and that there is no legally sound reason at this time to further narrow the buffer element to a particular species. The Examiner respectfully submits that the Applicant has misinterpreted the reason for the rejection, the rejection was made over dependent claim 43 because as Applicant states in their response "the buffer is important to the claimed invention and is recited in claim 1" and as such it is the Examiner's opinion that omitting the buffer element, which is important/essential according to claim 1 is in error, when the claimed invention is drawn to a composition comprising fentanyl or a pharmaceutically acceptable salt, a buffer, and excipient. Since, the buffer is indeed important to the invention as stated by Applicant the rejection of claim 43 for omitting an essential element stands.

## NEW REJECTIONS

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 15-16, 19-20, 22-25, 27-28, 30-32, 35-37, 39-40 and 42-43 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0160043 ('043).

The limitations of claims 1, 3-5 and 19-20 are taught:

- '043 teaches the drug-containing lozenges for use in the transmucosal delivery of medicaments to a patient (pg. 1, [0002]). '043 teaches that fentanyl is a preferred drug for use in the dissolvable dosage form (pg. 10, [0127] and example 4-5, claims 1, 22, 31). '043 further teaches binding agents, sweeteners, buffers, etc (pg. 6, [0079-0087], and example 4, claims 3, 14-15, 30-34, 39).
- '043 teaches sweeteners, such as aspartame (NutraSweet) and compressible confectioner's sugar, fructose, sorbitol, mannitol, xylitol, etc. (pg. 7, [0093]), and example 1 and 4 do only contain aspartame (NutraSweet) and compressible confectioner's sugar. Where the compressed sugar present in 20%, which is less than "sugar-free" as defined by the instant specification on pg. 9, lines 1-4

Art Unit: 1615

compositions containing "less than about 40 and preferably less than about 25%", further applicants own examples 1-6 teach using compressible confectioner's sugar in the sugar-free formulation.

- Further, example 2 of '043 is completely free from compressible sugar and only contains the non-sugar sweetener aspartame.

The limitations of claims 2, 32 and 42-43 are taught:

- '043 teaches including sugar such as compressible confectioner's sugar and fructose (pg. 7, [0093] and claim 3).

The limitations of claims 15-16, 22-28, and 30-31 are taught:

- '043 teaches in addition to the polyhydric alcohols above, binding agents such as various cellulose derivatives, microcrystalline cellulose, carboxymethylcellulose, etc. (pg. 7, [0089], claim 3).
- '043 teaches in addition to the polyhydric alcohols and binding agents that the buffering agents provide a favorable pH environment to stabilize the drug in the formulation and to optimize absorption of medicaments across the mucosal tissues of the mouth, etc. and that pH adjustment can air in producing a more palatable product with drugs which are either severely acidic or basic (pg. 4, [0042]; pg. 7, [0098-0099]). Further, '043 teaches buffering systems such as citric acid/sodium citrate and tromethamine (pg. 7, [0099]). Claims 32-33 of '043 teach a citrate buffer system and a phosphate buffer system.

The limitations of claims 35-37 and 39-40 are taught:

Art Unit: 1615

- Fentanyl is taught by '043 to range in amounts from 200 mg in a 2 g lozenge (pg. 12, [0154]), 0.1 to 1 mg of fentanyl for a child (example 5), or 5mg in 20 grams (25% by weight) in example 4.
- The composition of '043 teaches solid matrix that can be molded, compressed, dehydrated, freezed, also lozenges and compressed tablets for oral transmucosal dosage forms, and "hard candy" type (pg. 2, [0019-0020, 0032-0033]).
- Further, '043 teaches that the dosage form is potent and that the drug is introduced almost as fast as an injection, and less than 100 ng/mL in blood of the drug concentration (pg. 2-3, [0028-0030]). Thus it is the examiners opinion that this composition is just a bioequivalent as a composition containing fentanyl and sugar. Therefore '043 anticipates the instant claims 1-5, 15-16, 19-20, 22-25, 27-28, 30-31, 35-37 and 39-40.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 32-34, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0160043 ('043):



Art Unit: 1615

The limitations of claims 38 and 41 are taught:

- '043 is taught above and teaches a lozenge for the patient to suck or squeezed that can include sugar, such as confectioners sugar and fructose or sugar-free sweeteners.
- '043 does not teach a handle affixed to the lozenge or sugar in the amount of greater than 50% or 90% .

It would have been obvious to one of ordinary skill in the art at the time the invention was made to take the fentanyl composition made to for the patient to suck on in a 'hard candy' or lozenge form such as those taught by '043 and put a handle on it to make a 'sucker' or 'lollipop' type dosage form. It would have been obvious to one of ordinary skill in that art that such a composition of '043 could 'easily be removed by the patient or caregiver' (pg. 5, [0064]) and further that can be molded or formed into various shape, sizes, and molds as taught by '043 (pg. 2-3, [0020, 0033]). Furthermore, '043 teaches that sweeteners such as confectioners sugar and fructose can be employed in the composition and it would have been obvious to optimize the amount of sugar used in order to produce a 'palatable dosage form' as taught by '043 (pg. 7, [0093]). One of ordinary skill in the art would know how to optimize the ranges of '043, as the MPEP 2144.05 states "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Claims 1, 11, 17-18, 22-25, and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0160043 ('043) in view of 7,122,198 B1 ('198).

The limitations of claims 1, 11, 17-18, 22-25, and 28-29 are taught:

- '043 is taught above and teaches a lozenge comprising fentanyl is a preferred and further teaches binding agents, sweeteners, buffers (pg. 10, [0127] and example 1, 4-5, see claims 1, 3, 14-15, 22, 31-34, 39).
- '043 does not teach isomalt.
- '198 teaches a novel fast dissolving pharmaceutical composition in a solid dosage form with prolonged sweet taste which comprises (a) at least one pharmaceutically active agent (b) at least one water soluble sugar (c) at least one non-sugar sweetener in normal fast release form and (d) at least on non-sugar sweetener in a mucoadhesive slow release form (abstract, claim 1) and teaches fentanyl (col. 3, line 65) and sorbitol, xylitol, etc (water soluble sugar), isomalt, aspartame, etc (non-sugar sweetener) (claims 2-3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of '043 and '198 since both are drawn to dissolving pharmaceutical compositions comprising fentanyl, cellulose derivatives, sorbitol, aspartame, etc. One of ordinary skill in the art would have been motivated to combine the teachings of '043 and '198, since both teach a dosage form comprising a non-sugar sweetener such as aspartame. '198 further teaches that isomalt is also a known non-sugar sweetener for use in dissolving pharmaceutical compositions, as such one of ordinary skill in the art would have been motivated to use isomalt in the composition

taught by '043. As such the teachings of '043 and '198 are obvious over the instant claims.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-5, 11, 15-20, 22-25, and 27-43 have been considered but are not persuasive and are moot in view of the new grounds of rejection necessitated by applicants' amendments.

### ***Conclusions***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1615


### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany P. Barham whose telephone number is 571-272-6175. The examiner can normally be reached on M-F from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Examiner 1615

  
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